

<b>Notice of Allowability</b>	Application No.	Applicant(s)	
	10/791,278	SLUSHER ET AL.	
	Examiner	Art Unit	
	Susannah Lee	1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 31 August 2005.
2. ☒ The allowed claim(s) is/are 1,3-5,18,39,40 and 42.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>092105</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                       |
|   | 9. <input type="checkbox"/> Other _____.   |

### **DETAILED ACTION**

Claims 1-42 are pending in the instant application.

#### ***Priority***

This application claims benefit of 60/450,648, filed on 03/03/2003.

#### ***102 Rejection Withdrawn***

Applicant's arguments, see Remarks, filed on 31 August 2005, with respect to 102 Rejection have been fully considered and are persuasive. The 102 Rejection of the previous office action filed on 31 May 2005 has been withdrawn.

#### ***Election/Restrictions***

This application is in condition for allowance except for the presence of claims 1-5 (in part), 6-38, 39 (in part), and 41 to an invention non-elected without traverse on 05/05/2005. Applicant has given Examiner permission to cancel the nonelected claims via Examiner's Amendment to pass the case to issue.

Claims 1-5 (in part), 39 (in part), 40 and 42 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claim 18, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, is now subject to being rejoined. The restriction requirement filed on 05/31/2005 is hereby withdrawn and process claim 18 is hereby rejoined and fully examined for patentability under 37 CFR 1.104. In accordance with the Official Gazette notice, *supra*, process claims 14-17, 19-38 and 41, which do not depend from or otherwise include all the limitations of the allowable product, will NOT be rejoined and examined.

As stated in the previous office action, all compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.)

***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Suet Chong on 10/03/2005.

The application has been amended as follows:

**Delete** claims 2, 5-17, 19-38, and 41.

In claim 1, line 1, **delete** “, II or III” after the word formula I.

In claim 1, line 2, **delete** “II” and “III” and the accompanying figures.

In claim 1, line 9, **delete** “-O-, -S-,” after the word is.

In claim 1, line 9, **delete** “or –NR3-“ after the word –CR3R4.

In claim 1, line 11, **delete** “1,” after the word is.

In claim 1, line 11, **delete** “, 3, or 4” after the word 2.

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**Delete** claim 18 and **insert** “A method of treating peripheral neuropathy, comprising administering to a mammal in need of such inhibition, treatment or effect, an effective amount of a compound of formula I of claim 1”.

In claim 39, line 2, **delete** “, II or III” after the word formula I.

In claim 39, line 3, **delete** “II” and “III” and the accompanying figures.

In claim 39, line 10, **delete** “-O-, -S-,” after the word is.

In claim 39, line 10, **delete** “or -NR3-“ after the word -CR3R4.

In claim 39, line 12, **delete** “1,” after the word is.

In claim 39, line 12, **delete** “, 3, or 4” after the word 2.

#### ***Reasons for Allowance***

The present invention is directed to thiolactones and their methods of use for the treatment of a neurological disorder that is diabetic neuropathy. The closet prior art of record, U.S. Patent Num. 6,812,364 ('364 Patent), teaches substituted tetrahydro-2H-thiopyran compounds wherein the group corresponding to X is Ar instead of an alkyl chain like in the instant application. The instant compounds of Claims 40 and 42 are patentable because the prior art does not teach that X can be an alkyl chain.

The method of treating peripheral neuropathy is supported in the specification in paragraph 136, page 28, line 19 and page 13, line 3; page 14, line 6; page 16, line 4, etc... In addition, the state of the art supports the use of thiophene derivatives in the treatment of neuropathic pain, in particular peripheral neuropathy. See Expert Opin. Emerging Drugs (2005) 10(1): 95-108.

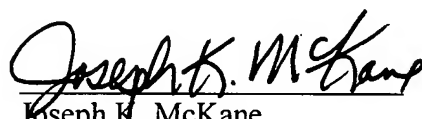
*Telephone Inquiry*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Lee whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susannah Lee  
Patent Examiner, AU 1626

  
Joseph R. McKane  
Supervisory Patent Examiner  
AU 1626  
Date: 10/06/2005